

**REMARKS UNDER 37 CFR § 1.111**

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1, 6-11 and 16-27, the only claims pending and currently under examination in this application.

The independent claims have been amended to substitute the generic term polyamide for the trademark "NYLON" in these claims. Support for this amendment is found in the specification at page 5, line 18, among other known locations. As such, no new matter has been added by this amendment and its entry by the Examiner is respectfully requested.

**Rejection under 35 U.S.C. §102(e)**

The rejection of Claims 1, 6-11 and 16-23 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,972,294 issued to Smith et al. has been maintained.

However, what is claimed in the present application is 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine or a salt thereof on a polyamide matrix.

The only actual composition that Smith discloses is a reagent test strip comprising a polysulfone membrane and 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine.

Smith suggests that other substrates may be suitable, such as polyamide. But he does not specifically disclose a strip that includes 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine or a salt thereof on a polyamide matrix.

Accordingly, the presently pending claims are not anticipated by Smith et al. and this rejection under 35 U.S.C. §102(e) should be withdrawn.

Rejection under 35 U.S.C. §103(a)

The rejection of Claims 24-27 under 35 U.S.C. §103(a) as obvious over Smith et al has been maintained. As pointed out above, Smith has been cited against the present application as 102 (e) art.

As such, Smith et al. does not qualify as prior art for purposes of 35 U.S.C. §103. 35 U.S.C. § 103 states in relevant part:

Subject matter developed by another person, which qualifies as prior art only under subsection (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention as made, owned by the same person **or subject to an obligation of assignment to the same person** (35 U.S.C. ' 103(c))

The present case and the Smith patent were both under obligation to assign to Lifescan at the time both inventions were made.

As such, Smith et al. does not qualify has prior art under 35 U.S.C. §103 against the present application. Accordingly, this rejection may be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Finally, Claims 1, 6-11 and 16-27 have been rejected under 35 U.S.C. §112, second paragraph for a number of issues.

With respect to the term "NYLON," the above amendments overcome this rejection.

With respect to the term "signal producing system," this term is clearly defined in the specification beginning at page 6, line 5, and is therefore not indefinite when read in light of the specification.

With respect to the term analyte oxidase, this term is clear when read in view of the specification at page 6, lines 24 ff, which states:

As indicated above, the hydrogen peroxide based signal producing systems include an enzyme that oxidizes the analyte and produces a corresponding amount of hydrogen peroxide, where by corresponding amount is meant that the amount of hydrogen peroxide that is produced is proportional to the amount of analyte present in the sample. The specific nature of this first enzyme necessarily depends on the nature of the analyte being assayed but is generally an oxidase. As such, the enzyme may be: glucose oxidase (where the analyte is glucose); cholesterol oxidase (where the analyte is cholesterol); alcohol oxidase (where the analyte is alcohol); formaldehyde dehydrogenase (where the analyte is formaldehyde), glutamate oxidase (where the analyte is L-glutamic acid), glycerol oxidase (where the analyte is glycerol), galactose oxidase (where the analyte is galactose), a ketoamine oxidase (where the analyte is a glycated protein, e.g., fructosamine), a 3-hydroxybutyrate dehydrogenase (where the analyte is a ketone body), L-ascorbate oxidase (where the analyte is ascorbic acid), lactate oxidase (where the analyte is lactic acid), leucine oxidase (where the analyte is leucine), malate oxidase (where the analyte is malic acid), pyruvate oxidase (where the analyte is pyruvic acid), urate oxidase (where the analyte is uric acid oxidase) and the like. Other oxidizing enzymes for use with these and other analytes of interest are known to those of skill in the art and may also be employed.

As such, this term is not indefinite.

In view of the above discussion, the Examiner is respectfully requested to withdraw the rejections under 35 U.S.C. §112, second paragraph.

**CONCLUSION**

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

If the Examiner finds that a Telephone Conference would expedite prosecution of this application, he is invited to contact the undersigned (650) 327-3400.

In the event that the transmittal letter is separated from this document and the Patent Office determines that extensions or other relief is required and/or fees are due applicants, the Applicant petitions for any required relief, including extensions of time, and authorize the Commissioner to charge our Deposit Account No. 50-0815, Order Number LIFE008, for any fees due in connection with the filing of this document. The Patent Office is not authorized to charge issue fees to our Deposit Account.

Respectfully submitted,  
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